

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC REPAIR  
SYSTEM PRODUCTS LIABILITY LITIGATION

MDL NO. 2327

**MASTER ANSWER AND JURY DEMAND OF DEFENDANT JOHNSON & JOHNSON  
TO FIRST AMENDED MASTER COMPLAINT**

Defendant Johnson & Johnson responds to Plaintiffs' Master Long Form Complaint and Jury Demand ("plaintiffs' Complaint") as follows:

**I. RESPONSE TO "PARTIES"<sup>1</sup>**

**A. Response to "Plaintiffs"**

1. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 1 of plaintiffs' Complaint and, therefore, denies those allegations.

2. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 2 of plaintiffs' Complaint and, therefore, denies those allegations.

**B. Response to "Defendants"**

3. In response to the first sentence of Paragraph 3 of plaintiffs' Complaint, Johnson & Johnson admits only that it is a business corporation organized under the laws of the State of New Jersey with its principal place of business at One Johnson & Johnson Plaza in New Brunswick, New Jersey. Johnson & Johnson further admits that it is a holding company that does not manufacture, market, distribute, sell or design any

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<sup>1</sup> The repetition of the Complaint's subheadings is done solely for organizational purposes and is not an admission as to their truth.

products or services. Johnson & Johnson further admits that its web site states that the Johnson & Johnson “Family of Companies comprises \* \* \* The world’s largest and most diverse medical devices and diagnostics company \* \* \*.” *See* [www.jnj.com](http://www.jnj.com) (accessed June 13, 2012). Johnson & Johnson denies the remaining allegations contained in Paragraph 3 of plaintiffs’ Complaint.

4. Johnson & Johnson admits that Ethicon, Inc. is a business corporation organized under the laws of the State of New Jersey with its principal place of business in Somerville, New Jersey and that Ethicon, Inc. is a wholly owned subsidiary of Johnson & Johnson.

5. Johnson & Johnson admits that Ethicon LLC has a manufacturing location in San Lorenzo, Puerto Rico, and that Ethicon LLC has manufactured certain pelvic floor repair products. Johnson & Johnson denies the remaining allegations contained in Paragraph 5 of plaintiffs’ Complaint.

6. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 6 of plaintiffs’ Complaint and, therefore, denies those allegations.

7. Johnson & Johnson admits only that Ethicon, Inc. has designed, manufactured, tested, trained, marketed, promoted, packaged, labeled, advertised, promoted and/or sold Prolene Mesh/Prolene Soft Mesh, Gynemesh, Gynemesh PS, TVT, TVT-Obturator (TVT-O), TVT-SECUR (TVT-S), TVT Exact, TVT Abbrevio, Prolift, Prolift + M, and Prosima for uses consistent with their packaging and labeling. Johnson & Johnson denies that it has designed, manufactured, tested, trained, marketed, promoted, packaged, labeled, advertised, promoted or sold any product. Johnson &

Johnson denies the remaining allegations contained in Paragraph 7 of plaintiffs' Complaint.

8. Johnson & Johnson admits only that Ethicon, Inc. has certain duties imposed on it by law and denies that Ethicon, Inc. breached any such duties. Johnson & Johnson denies the remaining allegations contained in Paragraph 8 of plaintiffs' Complaint.

## II. RESPONSE TO "JURISDICTION AND VENUE"

9. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 9 of plaintiffs' Complaint and, therefore, denies those allegations.

10. Paragraph 10 of plaintiffs' Complaint states a legal conclusion and requires no response by Johnson & Johnson.

11. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in the first sentence of Paragraph 11 of plaintiffs' Complaint and, therefore, denies those allegations. The second sentence of plaintiffs' Complaint states a legal conclusion and requires no response by Johnson & Johnson.

## III. RESPONSE TO "DEFENDANTS' PELVIC MESH PRODUCTS"

12. Johnson & Johnson admits only that Ethicon, Inc. has manufactured, marketed and sold Gynemesh for uses consistent with its packaging and labeling. Johnson & Johnson denies that it has manufactured, marketed or sold any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 12 of plaintiffs' Complaint.

13. Johnson & Johnson admits only that Ethicon, Inc. has manufactured, marketed and sold Prolene Mesh for uses consistent with its packaging and labeling. Johnson & Johnson denies that it has manufactured, marketed or sold any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 13 of plaintiffs' Complaint.

14. Johnson & Johnson admits only that Ethicon, Inc. has marketed and sold Prolift, Prolift Anterior, Prolift Posterior and Prolift Total for uses consistent with their packaging and labeling. Johnson & Johnson denies that it has marketed or sold any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 14 of plaintiffs' Complaint.

15. Johnson & Johnson admits only that Ethicon, Inc. has marketed and sold Prolift +M for uses consistent with its packaging and labeling. Johnson & Johnson denies that it has marketed or sold any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 15 of plaintiffs' Complaint.

16. Johnson & Johnson admits only that Ethicon, Inc. has marketed and sold Prosima for uses consistent with its packaging and labeling. Johnson & Johnson denies that it has marketed or sold any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 16 of plaintiffs' Complaint.

17. Johnson & Johnson admits only that Ethicon, Inc. has marketed and sold TVT, TVT-Obturator (TVT-O), TVT-SECUR (TVT-S), TVT Exact and TVT Abbrevio for uses consistent with their packaging and labeling. Johnson & Johnson denies that it has marketed or sold any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 17 of plaintiffs' Complaint.

18. Johnson & Johnson admits only that Ethicon, Inc. has designed and sold Prolene Mesh, Gynemesh, Prolift, Prosima, Prolift +M and TVT for uses consistent with their packaging and labeling. Johnson & Johnson denies that it has designed or sold any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 18 of plaintiffs' Complaint.

19. Johnson & Johnson admits only that Ethicon, Inc. has designed, patented, manufactured, labeled, marketed, sold and distributed certain "pelvic mesh products" for uses consistent with their packaging and labeling. Johnson & Johnson denies that it has designed, patented, manufactured, labeled, marketed, sold or distributed any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 19 of plaintiffs' Complaint.

### III. RESPONSE TO "FACTUAL BACKGROUND"

20. The first three sentences in Paragraph 20 of plaintiffs' Complaint make no allegations against Johnson & Johnson and require no response by Johnson & Johnson. In response to the fourth and fifth sentences in Paragraph 20 of plaintiffs' Complaint, Johnson & Johnson states that Ethicon, Inc.'s products and kits are manufactured and sold for uses consistent with their packaging and labeling. The last sentence in Paragraph 20 of plaintiffs' Complaint makes no allegation against Johnson & Johnson and requires no response by Johnson & Johnson. Johnson & Johnson denies the remaining allegations contained in Paragraph 20 of plaintiffs' Complaint.

21. Johnson & Johnson admits only that Ethicon, Inc.'s products are promoted for uses consistent with their packaging and labeling. Johnson & Johnson denies the remaining allegations contained in Paragraph 21 of plaintiffs' Complaint.

22. Johnson & Johnson admits only that certain of Ethicon, Inc.'s products contain polypropylene mesh. Johnson & Johnson denies the remaining allegations contained in Paragraph 22 of plaintiffs' Complaint.

23. Johnson & Johnson admits only that Ethicon, Inc. has complied with the mandates of the Food and Drug Administration ("FDA") and that the FDA regulations referenced in Paragraph 23 of plaintiffs' Complaint speak for themselves. Johnson & Johnson denies the remaining allegations contained in Paragraph 23 of plaintiffs' Complaint.

24. Johnson & Johnson admits only that Ethicon, Inc.'s products are safe and effective for uses consistent with their packaging and labeling. Johnson & Johnson denies the remaining allegations contained in Paragraph 24 of plaintiffs' Complaint.

25. Johnson & Johnson denies the allegations contained in Paragraph 25 of plaintiffs' Complaint.

26. Johnson & Johnson denies the allegations contained in Paragraph 26 of plaintiffs' Complaint.

27. Johnson & Johnson denies the allegations contained in Paragraph 27 of plaintiffs' Complaint.

28. Johnson & Johnson denies the allegations contained in Paragraph 28, including subparts (a) – (o), of plaintiffs' Complaint.

29. Johnson & Johnson denies the allegations contained in Paragraph 29 of plaintiffs' Complaint.

30. Johnson & Johnson denies the allegations contained in Paragraph 30 of plaintiffs' Complaint.

31. Johnson & Johnson denies the allegations contained in Paragraph 31 of plaintiffs' Complaint.

32. Johnson & Johnson states that the FDA Public Health Notification referenced in Paragraph 32 of plaintiffs' Complaint speaks for itself. Johnson & Johnson denies the remaining allegations contained in Paragraph 32 of plaintiffs' Complaint.

33. Johnson & Johnson states that the FDA Safety Communication referenced in Paragraph 33 of plaintiffs' Complaint speaks for itself. Johnson & Johnson denies the remaining allegations contained in Paragraph 30 of plaintiffs' Complaint.

34. Johnson & Johnson states that the FDA Safety Communication referenced in Paragraph 34 of plaintiffs' Complaint speaks for itself. Johnson & Johnson denies the remaining allegations contained in Paragraph 31 of plaintiffs' Complaint.

35. Johnson & Johnson denies the allegations contained in Paragraph 35 of plaintiffs' Complaint.

36. Johnson & Johnson denies the allegations contained in Paragraph 36 of plaintiffs' Complaint.

37. Johnson & Johnson states that the Committee Opinion referenced in Paragraph 37 of plaintiffs' Complaint speaks for itself. Johnson & Johnson denies the remaining allegations contained in Paragraph 34 of plaintiffs' Complaint.

38. Johnson & Johnson denies the allegations contained in Paragraph 38 of plaintiffs' Complaint.

39. Johnson & Johnson denies the allegations contained in Paragraph 39 of plaintiffs' Complaint.

40. Johnson & Johnson denies the allegations contained in Paragraph 40 of plaintiffs' Complaint.

41. Johnson & Johnson denies the allegations contained in Paragraph 41, including subparts (a) – (u), of plaintiffs' Complaint.

42. Johnson & Johnson denies the allegations contained in Paragraph 42 of plaintiffs' Complaint.

43. Johnson & Johnson denies the allegations contained in Paragraph 43 of plaintiffs' Complaint.

44. Johnson & Johnson denies the allegations contained in Paragraph 44 of plaintiffs' Complaint.

45. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 45 of plaintiffs' Complaint and, therefore, denies those allegations.

46. Johnson & Johnson denies the allegations contained in Paragraph 46 of plaintiffs' Complaint.

47. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 47 of plaintiffs' Complaint and, therefore, denies those allegations.

48. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 48 of plaintiffs' Complaint and, therefore, denies those allegations.



49. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 49 of plaintiffs' Complaint and, therefore, denies those allegations.

50. Johnson & Johnson states that the medical and scientific literature referenced in Paragraph 50 of plaintiffs' Complaint speaks for itself. Johnson & Johnson denies the remaining allegations contained in Paragraph 50 of plaintiffs' Complaint.

51. Johnson & Johnson denies the allegations contained in Paragraph 51 of plaintiffs' Complaint.

52. Johnson & Johnson denies the allegations contained in Paragraph 52 of plaintiffs' Complaint.

53. Johnson & Johnson denies the allegations contained in Paragraph 53 of plaintiffs' Complaint.

54. Johnson & Johnson denies the allegations contained in Paragraph 54, including subparts (a) – (l), of plaintiffs' Complaint.

55. Johnson & Johnson admits only that Ethicon, Inc. has certain duties imposed on it by law and denies that Ethicon, Inc. breached any such duties. Johnson & Johnson denies the remaining allegations contained in Paragraph 55 of plaintiffs' Complaint.

56. Johnson & Johnson denies the allegations contained in Paragraph 56 of plaintiffs' Complaint.

57. Johnson & Johnson denies the allegations contained in Paragraph 57 of plaintiffs' Complaint.

58. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 58 of plaintiffs' Complaint and, therefore, denies those allegations.

59. Johnson & Johnson denies the allegations contained in Paragraph 59 of plaintiffs' Complaint.

60. Johnson & Johnson denies the allegations contained in Paragraph 60 of plaintiffs' Complaint.

61. Johnson & Johnson denies the allegations contained in Paragraph 61 of plaintiffs' Complaint.

62. Johnson & Johnson admits only that Ethicon, Inc. has certain duties imposed on it by law and denies that Ethicon, Inc. breached any such duties. Johnson & Johnson denies the remaining allegations contained in Paragraph 62 of plaintiffs' Complaint.

63. Johnson & Johnson denies the allegations contained in Paragraph 63 of plaintiffs' Complaint.

64. Johnson & Johnson denies the allegations contained in Paragraph 64 of plaintiffs' Complaint.

65. Johnson & Johnson denies the allegations contained in Paragraph 65 of plaintiffs' Complaint.

66. Johnson & Johnson denies the allegations contained in Paragraph 66 of plaintiffs' Complaint.

67. Johnson & Johnson denies the allegations contained in Paragraph 67 of plaintiffs' Complaint.

68. Johnson & Johnson states that Ethicon, Inc.'s submissions to the FDA speak for themselves and denies the remaining allegations contained in Paragraph 68 of plaintiffs' Complaint.

69. Johnson & Johnson denies the allegations contained in Paragraph 69 of plaintiffs' Complaint.

70. Johnson & Johnson denies the allegations contained in Paragraph 70 of plaintiffs' Complaint.

71. Johnson & Johnson denies the allegations contained in Paragraph 71 of plaintiffs' Complaint.

72. Johnson & Johnson lacks sufficient knowledge or information to know what plaintiffs or plaintiffs' healthcare providers knew, and Johnson & Johnson denies the remaining allegations contained in Paragraph 72 of plaintiffs' Complaint.

73. Johnson & Johnson lacks sufficient knowledge or information to know what plaintiffs knew, and Johnson & Johnson denies the remaining allegations contained in Paragraph 73 of plaintiffs' Complaint.

74. Johnson & Johnson admits only that Ethicon, Inc.'s products are safe and effective for uses consistent with their packaging and labeling. Johnson & Johnson denies the remaining allegations contained in Paragraph 74 of plaintiffs' Complaint.

75. Johnson & Johnson denies the allegations contained in Paragraph 75 of plaintiffs' Complaint.

76. Johnson & Johnson denies the allegations contained in Paragraph 76 of plaintiffs' Complaint.

77. Johnson & Johnson denies the allegations contained in Paragraph 77 of plaintiffs' Complaint.

78. Johnson & Johnson denies the allegations contained in Paragraph 78 of plaintiffs' Complaint.

79. Johnson & Johnson denies the allegations contained in Paragraph 79 of plaintiffs' Complaint.

80. Johnson & Johnson denies the allegations contained in Paragraph 80 of plaintiffs' Complaint.

81. Johnson & Johnson denies the allegations contained in Paragraph 81 of plaintiffs' Complaint.

#### IV. RESPONSE TO "FRAUDULENT CONCEALMENT"

82. Johnson & Johnson denies the allegations contained in Paragraph 82 of plaintiffs' Complaint.

83. Johnson & Johnson denies the allegations contained in Paragraph 83 of plaintiffs' Complaint.

84. Johnson & Johnson admits only that Ethicon, Inc. has certain duties imposed on it by law and denies that Ethicon, Inc. breached any such duties. Johnson & Johnson denies the remaining allegations contained in Paragraph 84 of plaintiffs' Complaint.

85. Johnson & Johnson denies the allegations contained in Paragraph 85 of plaintiffs' Complaint.

86. Johnson & Johnson denies the allegations contained in Paragraph 86 of plaintiffs' Complaint.

87. Johnson & Johnson denies the allegations contained in Paragraph 87 of plaintiffs' Complaint.

88. Johnson & Johnson denies the allegations contained in Paragraph 88 of plaintiffs' Complaint.

#### V. RESPONSE TO "CAUSES OF ACTION"

##### RESPONSE TO "COUNT I"

89. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Paragraphs 1-88 of plaintiffs' Complaint.

90. Johnson & Johnson admits only that Ethicon, Inc. has certain duties imposed on it by law and denies that Ethicon, Inc. breached any such duties. Johnson & Johnson denies the remaining allegations contained in Paragraph 90 of plaintiffs' Complaint.

91. Johnson & Johnson denies the allegations contained in Paragraph 91, including subparts (a) – (j), of plaintiffs' Complaint.

92. Johnson & Johnson denies the allegations contained in Paragraph 92, including subparts (a) – (b), of plaintiffs' Complaint.

93. Johnson & Johnson denies the allegations contained in Paragraph 93, including subparts (a) – (b), of plaintiffs' Complaint.

94. Johnson & Johnson denies the allegations contained in Paragraph 94 of plaintiffs' Complaint.

In response to the unnumbered "Wherefore" Paragraph at the conclusion of Count I of plaintiffs' Complaint, Johnson & Johnson denies that plaintiffs are entitled to any recovery or any form of relief whatsoever.

RESPONSE TO “COUNT II”

95. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Paragraphs 1-94 of plaintiffs’ Complaint.

96. Johnson & Johnson denies the allegations contained in Paragraph 96 of plaintiffs’ Complaint.

97. Johnson & Johnson denies the allegations contained in Paragraph 97 of plaintiffs’ Complaint.

98. Johnson & Johnson denies the allegations contained in Paragraph 98 of plaintiffs’ Complaint.

99. Johnson & Johnson denies the allegations contained in Paragraph 99 of plaintiffs’ Complaint.

100. Johnson & Johnson denies the allegations contained in Paragraph 100 of plaintiffs’ Complaint.

101. Johnson & Johnson denies the allegations contained in Paragraph 101 of plaintiffs’ Complaint.

In response to the unnumbered “Wherefore” Paragraph at the conclusion of Count II of plaintiffs’ Complaint, Johnson & Johnson denies that plaintiffs are entitled to any recovery or any form of relief whatsoever.

RESPONSE TO “COUNT III”

102. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Paragraphs 1-101 of plaintiffs’ Complaint.

103. Johnson & Johnson denies the allegations contained in Paragraph 103 of plaintiffs’ Complaint.

104. Johnson & Johnson denies the allegations contained in Paragraph 104 of plaintiffs' Complaint.

105. Johnson & Johnson denies the allegations contained in Paragraph 105 of plaintiffs' Complaint.

106. Johnson & Johnson denies the allegations contained in Paragraph 106, including subparts (a) – (r), of plaintiffs' Complaint.

107. Johnson & Johnson denies the allegations contained in Paragraph 107 of plaintiffs' Complaint.

108. Johnson & Johnson denies the allegations contained in Paragraph 108 of plaintiffs' Complaint.

109. Johnson & Johnson denies the allegations contained in Paragraph 109 of plaintiffs' Complaint.

In response to the unnumbered "Wherefore" Paragraph at the conclusion of Count III of plaintiffs' Complaint, Johnson & Johnson denies that plaintiffs are entitled to any recovery or any form of relief whatsoever.

#### RESPONSE TO "COUNT IV"

110. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Paragraphs 1-109 of plaintiffs' Complaint. Johnson & Johnson denies the remaining allegations contained in Paragraph 110 of plaintiffs' Complaint.

111. Johnson & Johnson denies the allegations contained in Paragraph 111 of plaintiffs' Complaint.

112. Paragraph 112 of plaintiffs' Complaint makes no allegation against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent that a response is required, Johnson & Johnson denies the allegations contained in Paragraph 112 of plaintiffs' Complaint.

113. Paragraph 113 of plaintiffs' Complaint makes no allegation against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent that a response is required, Johnson & Johnson denies the allegations contained in Paragraph 113 of plaintiffs' Complaint.

114. Johnson & Johnson denies the allegations contained in Paragraph 114 of plaintiffs' Complaint.

In response to the unnumbered "Wherefore" Paragraph at the conclusion of Count IV of plaintiffs' Complaint, Johnson & Johnson denies that plaintiffs are entitled to any recovery or any form of relief whatsoever.

#### RESPONSE TO "COUNT V"

115. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Paragraphs 1-114 of plaintiffs' Complaint.

116. Johnson & Johnson denies the allegations contained in Paragraph 116, including subparts (a) – (i), of plaintiffs' Complaint.

117. Johnson & Johnson denies the allegations contained in Paragraph 117 of plaintiffs' Complaint.

118. Johnson & Johnson denies the allegations contained in Paragraph 118 of plaintiffs' Complaint.



In response to the unnumbered “Wherefore” Paragraph at the conclusion of Count V of plaintiffs’ Complaint, Johnson & Johnson denies that plaintiffs are entitled to any recovery or any form of relief whatsoever.

RESPONSE TO “COUNT VI”

119. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Paragraphs 1-118 of plaintiffs’ Complaint.

120. Johnson & Johnson denies the allegations contained in Paragraph 120 of plaintiffs’ Complaint.

121. Johnson & Johnson denies the allegations contained in Paragraph 121 of plaintiffs’ Complaint.

122. Johnson & Johnson denies the allegations contained in Paragraph 122 of plaintiffs’ Complaint.

123. Johnson & Johnson denies the allegations contained in Paragraph 123, including subparts (a) – (n), of plaintiffs’ Complaint.

124. Johnson & Johnson admits only that Ethicon, Inc. has certain duties imposed on it by law and denies that Ethicon, Inc. breached any such duties. Johnson & Johnson denies the remaining allegations contained in Paragraph 124 of plaintiffs’ Complaint.

125. Johnson & Johnson denies the allegations contained in Paragraph 125 of plaintiffs’ Complaint.

126. Johnson & Johnson denies the allegations contained in Paragraph 126 of plaintiffs’ Complaint.

127. Johnson & Johnson lacks sufficient knowledge or information to know what plaintiffs knew, and Johnson & Johnson denies the remaining allegations contained in Paragraph 127 of plaintiffs' Complaint.

128. Johnson & Johnson denies the allegations contained in Paragraph 128 of plaintiffs' Complaint.

129. Johnson & Johnson denies the allegations contained in Paragraph 129 of plaintiffs' Complaint.

130. Johnson & Johnson denies the allegations contained in Paragraph 130 of plaintiffs' Complaint.

131. Johnson & Johnson denies the allegations contained in Paragraph 131 of plaintiffs' Complaint.

132. Johnson & Johnson admits only that Ethicon, Inc. has certain duties imposed on it by law and denies that Ethicon, Inc. breached any such duties. Johnson & Johnson denies the remaining allegations contained in Paragraph 132 of plaintiffs' Complaint.

133. Johnson & Johnson denies the allegations contained in Paragraph 133 of plaintiffs' Complaint.

134. Johnson & Johnson denies the allegations contained in Paragraph 134 of plaintiffs' Complaint.

135. Johnson & Johnson denies the allegations contained in Paragraph 135 of plaintiffs' Complaint.

136. Johnson & Johnson denies the allegations contained in Paragraph 136 of plaintiffs' Complaint.

137. Johnson & Johnson denies the allegations contained in Paragraph 137 of plaintiffs' Complaint.

138. Johnson & Johnson states that Ethicon, Inc.'s submissions to the FDA speak for themselves and denies the remaining allegations contained in Paragraph 138 of plaintiffs' Complaint.

139. Johnson & Johnson denies the allegations contained in Paragraph 139 of plaintiffs' Complaint.

140. Johnson & Johnson denies the allegations contained in Paragraph 140 of plaintiffs' Complaint.

141. Johnson & Johnson denies the allegations contained in Paragraph 141 of plaintiffs' Complaint.

142. Johnson & Johnson denies the allegation contained in Paragraph 142 of plaintiffs' Complaint.

143. Johnson & Johnson denies the allegations contained in Paragraph 143 of plaintiffs' Complaint.

144. Johnson & Johnson lacks sufficient knowledge or information to know what plaintiffs or plaintiffs' healthcare providers knew, and Johnson & Johnson denies the remaining allegations contained in Paragraph 144 of plaintiffs' Complaint.

145. Johnson & Johnson lacks sufficient knowledge or information to know what plaintiffs knew, and Johnson & Johnson denies the remaining allegations contained in Paragraph 145 of plaintiffs' Complaint.

146. Johnson & Johnson denies the allegations contained in Paragraph 146 of plaintiffs' Complaint.

147. Johnson & Johnson denies the allegations contained in Paragraph 147 of plaintiffs' Complaint.

In response to the unnumbered "Wherefore" Paragraph at the conclusion of Count VI of plaintiffs' Complaint, Johnson & Johnson denies that plaintiffs are entitled to any recovery or any form of relief whatsoever.

RESPONSE TO "COUNT VII"

148. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Paragraphs 1-147 of plaintiffs' Complaint.

149. Paragraph 149 of plaintiffs' Complaint makes no allegation against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent that a response is required, Johnson & Johnson denies the allegations contained in Paragraph 149 of plaintiffs' Complaint.

150. Johnson & Johnson denies the allegations contained in Paragraph 150 of plaintiffs' Complaint.

151. Johnson & Johnson denies the allegations contained in Paragraph 151 of plaintiffs' Complaint.

152. Johnson & Johnson denies the allegations contained in Paragraph 152, including subparts (a) – (c), of plaintiffs' Complaint.

153. Johnson & Johnson denies the allegations contained in Paragraph 153 of plaintiffs' Complaint.

154. Johnson & Johnson denies the allegations contained in Paragraph 154 of plaintiffs' Complaint.

155. Johnson & Johnson denies the allegations contained in Paragraph 155 of plaintiffs' Complaint.

156. Johnson & Johnson denies the allegations contained in Paragraph 156 of plaintiffs' Complaint.

In response to the unnumbered "Wherefore" Paragraph at the conclusion of Count VII of plaintiffs' Complaint, Johnson & Johnson denies that plaintiffs are entitled to any recovery or any form of relief whatsoever.

#### RESPONSE TO "COUNT VIII"

157. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Paragraphs 1-156 of plaintiffs' Complaint.

158. Johnson & Johnson denies the allegations contained in Paragraph 158 of plaintiffs' Complaint.

159. Johnson & Johnson denies the allegations contained in Paragraph 159 of plaintiffs' Complaint.

160. Johnson & Johnson states that the publication referenced in Paragraph 160 of plaintiffs' Complaint speaks for itself. Johnson & Johnson denies the remaining allegations contained in Paragraph 157 of plaintiffs' Complaint.

161. Johnson & Johnson denies the allegations contained in Paragraph 161 of plaintiffs' Complaint.

162. Johnson & Johnson denies the allegations contained in Paragraph 162 of plaintiffs' Complaint.

163. Johnson & Johnson denies the allegations contained in Paragraph 163 of plaintiffs' Complaint.

164. Johnson & Johnson denies the allegations contained in Paragraph 164 of plaintiffs' Complaint.

In response to the unnumbered "Wherefore" Paragraph at the conclusion of Count VIII of plaintiffs' Complaint, Johnson & Johnson denies that plaintiffs are entitled to any recovery or any form of relief whatsoever.

RESPONSE TO "COUNT IX"

165. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Paragraphs 1-164 of plaintiffs' Complaint. Johnson & Johnson denies the remaining allegations contained in Paragraph 165 of plaintiffs' Complaint.

166. Johnson & Johnson denies the allegations contained in Paragraph 166 of plaintiffs' Complaint.

167. Johnson & Johnson denies the allegations contained in Paragraph 167 of plaintiffs' Complaint.

168. Johnson & Johnson denies the allegations contained in Paragraph 168 of plaintiffs' Complaint.

169. Johnson & Johnson denies the allegations contained in Paragraph 169 of plaintiffs' Complaint.

In response to the unnumbered "Wherefore" Paragraph at the conclusion of Count IX of plaintiffs' Complaint, Johnson & Johnson denies that plaintiffs are entitled to any recovery or any form of relief whatsoever.

RESPONSE TO "COUNT X"

170. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Paragraphs 1-169 of plaintiffs' Complaint.

171. Johnson & Johnson denies the allegations contained in Paragraph 171 of plaintiffs' Complaint.

172. Johnson & Johnson denies the allegations contained in Paragraph 172 of plaintiffs' Complaint.

173. Johnson & Johnson denies the allegations contained in Paragraph 173 of plaintiffs' Complaint.

In response to the unnumbered "Wherefore" Paragraph at the conclusion of Count X of plaintiffs' Complaint, Johnson & Johnson denies that plaintiffs are entitled to any recovery or any form of relief whatsoever.

#### RESPONSE TO "COUNT XI"

174. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Paragraphs 1-173 of plaintiffs' Complaint.

175. Johnson & Johnson admits only that Ethicon, Inc. has manufactured, distributed, advertised, promoted and sold certain "pelvic mesh products." Johnson & Johnson denies that it has manufactured, distributed, advertised, promoted or sold any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 175 of plaintiffs' Complaint.

176. Johnson & Johnson admits only that Ethicon, Inc.'s products are safe, fit and of merchantable quality for uses consistent with their packaging and labeling. Johnson & Johnson denies the remaining allegations contained in Paragraph 176 of plaintiffs' Complaint.

177. Johnson & Johnson denies the allegations contained in Paragraph 177 of plaintiffs' Complaint.

178. Johnson & Johnson denies the allegations contained in Paragraph 178 of plaintiffs' Complaint.

179. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 179 of plaintiffs' Complaint and, therefore, denies those allegations.

180. Johnson & Johnson denies the allegations contained in Paragraph 180, including subparts (a) – (c), of plaintiffs' Complaint.

181. Johnson & Johnson denies the allegations contained in Paragraph 181 of plaintiffs' Complaint.

182. Johnson & Johnson denies the allegations contained in Paragraph 182 of plaintiffs' Complaint.

183. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 183 of plaintiffs' Complaint and, therefore, denies those allegations.

184. Johnson & Johnson denies the allegations contained in Paragraph 184 of plaintiffs' Complaint.

185. Johnson & Johnson denies the allegations contained in Paragraph 185 of plaintiffs' Complaint.

186. Johnson & Johnson denies the allegations contained in Paragraph 186 of plaintiffs' Complaint.



In response to the unnumbered “Wherefore” Paragraph at the conclusion of Count XI of plaintiffs’ Complaint, Johnson & Johnson denies that plaintiffs are entitled to any recovery or any form of relief whatsoever.

RESPONSE TO “COUNT XII”

187. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Paragraphs 1-186 of plaintiffs’ Complaint.

188. Johnson & Johnson admits only that Ethicon, Inc. has manufactured, distributed, advertised, promoted and sold certain “pelvic mesh products.” Johnson & Johnson denies that it has manufactured, distributed, advertised, promoted or sold any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 188 of plaintiffs’ Complaint.

189. Johnson & Johnson denies the allegations contained in Paragraph 189 of plaintiffs’ Complaint.

190. Johnson & Johnson denies the allegations contained in Paragraph 190 of plaintiffs’ Complaint.

191. Johnson & Johnson denies the allegations contained in Paragraph 191 of plaintiffs’ Complaint.

192. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 192 of plaintiffs’ Complaint and, therefore, denies those allegations.

193. Johnson & Johnson denies the allegations contained in Paragraph 193, including subparts (a) – (c) of plaintiffs’ Complaint.

194. Johnson & Johnson denies the allegations contained in Paragraph 194 of plaintiffs' Complaint.

195. Johnson & Johnson denies the allegations contained in Paragraph 195 of plaintiffs' Complaint.

196. Johnson & Johnson denies the allegations contained in Paragraph 196 of plaintiffs' Complaint.

In response to the unnumbered "Wherefore" Paragraph at the conclusion of Count XII of plaintiffs' Complaint, Johnson & Johnson denies that plaintiffs are entitled to any recovery or any form of relief whatsoever.

#### RESPONSE TO "COUNT XIII"

197. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Paragraphs 1-196 of plaintiffs' Complaint.

198. Johnson & Johnson denies the allegations contained in Paragraph 198 of plaintiffs' Complaint.

199. Johnson & Johnson denies the allegations contained in Paragraph 199 of plaintiffs' Complaint.

200. Johnson & Johnson denies the allegations contained in Paragraph 200 of plaintiffs' Complaint.

201. Johnson & Johnson denies the allegations contained in Paragraph 201, including subparts (a) – (c), of plaintiffs' Complaint.

202. Johnson & Johnson denies the allegations contained in Paragraph 202 of plaintiffs' Complaint.

203. Johnson & Johnson admits only that Ethicon, Inc. has certain duties imposed on it by law and denies that Ethicon, Inc. breached any such duties. Johnson & Johnson denies the remaining allegations contained in Paragraph 203 of plaintiffs' Complaint.

204. Johnson & Johnson denies the allegations contained in Paragraph 204 of plaintiffs' Complaint.

205. Johnson & Johnson denies the allegations contained in Paragraph 205 of plaintiffs' Complaint.

206. Johnson & Johnson denies the allegations contained in Paragraph 206 of plaintiffs' Complaint.

207. Johnson & Johnson denies the allegations contained in Paragraph 207 of plaintiffs' Complaint.

208. Johnson & Johnson denies the allegations contained in Paragraph 208 of plaintiffs' Complaint.

209. Johnson & Johnson denies the allegations contained in Paragraph 209 of plaintiffs' Complaint.

210. Johnson & Johnson denies the allegations contained in Paragraph 210 of plaintiffs' Complaint.

211. Johnson & Johnson denies the allegations contained in Paragraph 211 of plaintiffs' Complaint.

212. Johnson & Johnson denies the allegations contained in Paragraph 212 of plaintiffs' Complaint.

213. Johnson & Johnson denies the allegations contained in Paragraph 213 of plaintiffs' Complaint.

214. Johnson & Johnson denies the allegations contained in Paragraph 214 of plaintiffs' Complaint.

215. Johnson & Johnson denies the allegations contained in Paragraph 215 of plaintiffs' Complaint.

In response to the unnumbered "Wherefore" Paragraph at the conclusion of Count XIII of plaintiffs' Complaint, Johnson & Johnson denies that plaintiffs are entitled to any recovery or any form of relief whatsoever.

#### RESPONSE TO "COUNT XIV"

216. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Paragraphs 1-215 of plaintiffs' Complaint.

217. Johnson & Johnson denies the allegations contained in Paragraph 217 of plaintiffs' Complaint.

218. Johnson & Johnson denies the allegations contained in Paragraph 218 of plaintiffs' Complaint.

219. Paragraph 219 of plaintiffs' Complaint makes no allegation against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent that a response is required, Johnson & Johnson denies the allegations contained in Paragraph 219 of plaintiffs' Complaint.

220. Johnson & Johnson denies the allegations contained in Paragraph 220 of plaintiffs' Complaint.

In response to the unnumbered “Wherefore” Paragraph at the conclusion of Count XIV of plaintiffs’ Complaint, Johnson & Johnson denies that plaintiffs are entitled to any recovery or any form of relief whatsoever.

RESPONSE TO “COUNT XV”

221. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Paragraphs 1-220 of plaintiffs’ Complaint.

222. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 222 of plaintiffs’ Complaint and, therefore, denies those allegations.

223. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 223 of plaintiffs’ Complaint and, therefore, denies those allegations.

224. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 224 of plaintiffs’ Complaint and, therefore, denies those allegations.

225. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 225 of plaintiffs’ Complaint and, therefore, denies those allegations.

In response to the unnumbered “Wherefore” Paragraph at the conclusion of Count XV of plaintiffs’ Complaint, Johnson & Johnson denies that plaintiffs are entitled to any recovery or any form of relief whatsoever.

RESPONSE TO “COUNT XVI”

226. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Paragraphs 1-225 of plaintiffs' Complaint.

227. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 227 of plaintiffs' Complaint and, therefore, denies those allegations.

228. Johnson & Johnson denies the allegations contained in Paragraph 228 of plaintiffs' Complaint.

229. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 229 of plaintiffs' Complaint and, therefore, denies those allegations.

230. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 230 of plaintiffs' Complaint and, therefore, denies those allegations.

231. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 231 of plaintiffs' Complaint and, therefore, denies those allegations.

232. Johnson & Johnson denies the allegations contained in Paragraph 232 of plaintiffs' Complaint.

In response to the unnumbered "Wherefore" Paragraph at the conclusion of Count XVI of plaintiffs' Complaint, Johnson & Johnson denies that plaintiffs are entitled to any recovery or any form of relief whatsoever.

#### RESPONSE TO "COUNT XVII"

233. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Paragraphs 1-232 of plaintiffs' Complaint.

234. Johnson & Johnson denies the allegations contained in Paragraph 234 of plaintiffs' Complaint.

235. Johnson & Johnson denies the allegations contained in Paragraph 235 of plaintiffs' Complaint.

236. Johnson & Johnson denies the allegations contained in Paragraph 236 of plaintiffs' Complaint.

237. Johnson & Johnson denies the allegations contained in Paragraph 237 of plaintiffs' Complaint.

238. Johnson & Johnson denies the allegations contained in Paragraph 238 of plaintiffs' Complaint.

239. Johnson & Johnson denies the allegations contained in Paragraph 239 of plaintiffs' Complaint.

240. Johnson & Johnson denies the allegations contained in Paragraph 240 of plaintiffs' Complaint.

241. Johnson & Johnson denies the allegations contained in Paragraph 241 of plaintiffs' Complaint.

242. Johnson & Johnson denies the allegations contained in Paragraph 242 of plaintiffs' Complaint.

243. Johnson & Johnson denies the allegations contained in Paragraph 243 of plaintiffs' Complaint.

244. Johnson & Johnson denies the allegations contained in Paragraph 244 of plaintiffs' Complaint.

245. Johnson & Johnson denies the allegations contained in Paragraph 245 of plaintiffs' Complaint.

246. Johnson & Johnson denies the allegations contained in Paragraph 246 of plaintiffs' Complaint.

247. Johnson & Johnson denies the allegations contained in Paragraph 247 of plaintiffs' Complaint.

248. Johnson & Johnson denies the allegations contained in Paragraph 248 of plaintiffs' Complaint.

In response to the unnumbered "Wherefore" Paragraph at the conclusion of Count XVII of plaintiffs' Complaint, Johnson & Johnson denies that plaintiffs are entitled to any recovery or any form of relief whatsoever.

#### RESPONSE TO "COUNT XVIII"

249. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in Paragraphs 1-248 of plaintiffs' Complaint.

250. Paragraph 250 of plaintiffs' Complaint makes no allegation against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent that a response is required, Johnson & Johnson denies the allegations contained in Paragraph 250 of plaintiffs' Complaint.

251. Paragraph 251 of plaintiffs' Complaint makes no allegation against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent that



a response is required, Johnson & Johnson denies the allegations contained in Paragraph 251 of plaintiffs' Complaint.

252. Paragraph 252 of plaintiffs' Complaint makes no allegation against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent that a response is required, Johnson & Johnson denies the allegations contained in Paragraph 252 of plaintiffs' Complaint.

253. Johnson & Johnson denies the allegations contained in Paragraph 253 of plaintiffs' Complaint.

#### V. RESPONSE TO "PRAYER FOR RELIEF"

In response to the unnumbered "Wherefore" Paragraph in plaintiffs' "Prayer for Relief," Johnson & Johnson demands a jury trial and denies that plaintiffs are entitled to any recovery, including subparts (1) – (9), or any form of relief whatsoever, and Johnson & Johnson respectfully requests that the Master Long Form Complaint and Jury Demand be dismissed with prejudice with all costs assessed to plaintiffs and for any such other general or special relief as may be appropriate.

#### **SEPARATE DEFENSES**

##### **FIRST DEFENSE**

The plaintiffs' claims against Johnson & Johnson are barred because Johnson & Johnson does not design, develop, manufacture, market, promote or sell any product(s) allegedly at issue in this action.

##### **SECOND DEFENSE**

Johnson & Johnson has never had possession and control over the products at issue in this action, and therefore the Complaint as to each cause of action fails to state a claim against Johnson & Johnson.

**THIRD DEFENSE**

The Complaint fails to state a cause of action upon which relief can be granted.

**FOURTH DEFENSE**

The Complaint fails to state a cause of action upon which relief can be granted due to lack of adequate product identification.

**FIFTH DEFENSE**

Plaintiffs' claims are barred for lack of subject matter jurisdiction.

**SIXTH DEFENSE**

Plaintiffs' claims are barred for lack of personal jurisdiction.

**SEVENTH DEFENSE**

The Complaint must be dismissed because plaintiffs provided insufficient process.

**EIGHTH DEFENSE**

The Complaint must be dismissed because plaintiffs provided insufficient service of process.

**NINTH DEFENSE**

Plaintiffs may be barred from bringing some of the claims alleged in the Complaint because plaintiffs may lack standing and/or capacity to bring such claims.

**TENTH DEFENSE**

Plaintiffs may have failed to join indispensable parties or real parties in interest necessary for the just adjudication of this matter.

**ELEVENTH DEFENSE**

Venue in this Court is improper, and this matter should be dismissed on intra-state or interstate forum non conveniens grounds.

**TWELFTH DEFENSE**

Certain of plaintiffs' claims and remedies and the defenses thereto are governed by the laws of a foreign jurisdiction, i.e., a state other than that where the original suit was filed or where the suit has been transferred and is pending, or the laws of the United States.

**THIRTEENTH DEFENSE**

Plaintiffs' alleged causes of action have been improperly joined under the applicable Rules of Civil Procedure and the laws of the applicable state.

**FOURTEENTH DEFENSE**

The improper joinder of plaintiffs' alleged causes of action violate the procedural and substantive due process rights of Johnson & Johnson under the Constitutions of the United States of America and the applicable state.

**FIFTEENTH DEFENSE**

Johnson & Johnson is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute of the transferor court and any other state whose law is deemed to apply in this case.

**SIXTEENTH DEFENSE**

Johnson & Johnson specifically pleads as to plaintiffs' fraud, fraud by concealment and negligent misrepresentation claims, all affirmative defenses available to Johnson & Johnson under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

**SEVENTEENTH DEFENSE**

Plaintiffs' claims are barred by the doctrine of federal preemption, as established by statute, including the preemption provision of the Medical Device Amendments, 21 U.S.C. §

360k(a), to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., and by state and federal case law, and are barred by the Supremacy Clause of the United States Constitution, because the products at issue are regulated by the U.S. Food and Drug Administration (“FDA”) under the Medical Device Amendments, 21 U.S.C. § 360k, et seq., to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., and other federal statutes and regulation.

#### **EIGHTEENTH DEFENSE**

At all relevant times, Johnson & Johnson was in full compliance with all applicable federal statutes and regulations, including but not limited to the Medical Device Amendments, 21 U.S.C. § 360k, et seq., to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., and other federal statutes and regulations, and plaintiffs’ claims are accordingly barred.

#### **NINETEENTH DEFENSE**

Plaintiffs’ claims against Johnson & Johnson are expressly and/or impliedly preempted by federal law, including but not limited to, the regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. *See* 21 U.S.C. § 301 *et seq.*; *see also* Fed. Reg. 3922 (Jan. 24, 2006).

#### **TWENTIETH DEFENSE**

Plaintiffs’ claims are barred because Johnson & Johnson complied with all applicable state and federal statutes regarding the products at issue including the requirements and regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. In the event that plaintiffs’ claims are not barred, Johnson & Johnson is entitled to a presumption that the products at issue are free from any defect or defective condition as the plans or design for the products at issue or the methods and techniques of manufacturing, inspecting, and testing the products at issue were in conformity with government standards

established for the industry that were in existence at the time the plans or designs for the products at issue or the methods and techniques of manufacturing, inspecting, and testing the products at issue were adopted.

**TWENTY-FIRST DEFENSE**

Plaintiffs' claims are barred, in whole or in part, by the deference that federal and state constitutional law and federal and state common law give to discretionary actions by the FDA under the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and regulations promulgated there under.

**TWENTY-SECOND DEFENSE**

Plaintiffs' claims are governed and barred, in whole or in part, by Sections 2, 4, and 6 of The Restatement (Third) of Torts (including the comments thereto) because Johnson & Johnson complied with all applicable statutes and with the requirements and regulations of the FDA.

**TWENTY-THIRD DEFENSE**

Any claims by plaintiffs relating to alleged communications with regulatory agencies in the United States government are barred in whole or in part by operation of applicable law, including the First Amendment rights of Johnson & Johnson to petition the government.

**TWENTY-FOURTH DEFENSE**

Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under the law with determining the content of warnings and labeling for medical devices.

**TWENTY-FIFTH DEFENSE**

Plaintiffs cannot state a claim with regard to warnings and labeling for medical devices because the remedy sought by plaintiffs is subject to the exclusive regulation of FDA.

**TWENTY-SIXTH DEFENSE**

Plaintiffs' claim for punitive damages is barred because the products at issue were manufactured and labeled in accordance with the terms of FDA's clearance of the products at issue.

**TWENTY-SEVENTH DEFENSE**

Plaintiffs' claims are barred in whole or in part by plaintiffs' failure to assert a safer design for any of the products at issue.

**TWENTY-EIGHTH DEFENSE**

Plaintiffs' claims are barred in whole or in part because the products at issue provided a benefit to users of such products and greatly outweighed any risk created by using such products, any risk could not have been avoided through the use of the highest standards of scientific and technical knowledge available at the time, the benefit provided to users could not be achieved in another manner with less risk, and adequate warnings concerning the risk were provided.

**TWENTY-NINTH DEFENSE**

Johnson & Johnson made no express or implied representations or warranties of any kind to plaintiffs, nor did plaintiffs rely on any representations or warranties made by Johnson & Johnson to others. To the extent plaintiffs relied upon any representations or warranties, such reliance was unjustified.

**THIRTIETH DEFENSE**

Any express or implied warranties alleged to have been made by Johnson & Johnson were disclaimed.

**THIRTY-FIRST DEFENSE**

Johnson & Johnson did not make nor did it breach any express or implied warranties and/or breach any warranties created by law. To the extent that plaintiffs rely on any theory of breach of warranty, such claims are barred by applicable law, by the lack of privity between plaintiffs and Johnson & Johnson, and/or by plaintiffs' failure to give Johnson & Johnson timely notice of the alleged breach of warranty and an opportunity to cure. Johnson & Johnson further specifically pleads as to any breach of warranty claim all affirmative defenses available to Johnson & Johnson under the Uniform Commercial Code, as enacted in the State of New Jersey or any other state whose law is deemed to apply in this case, and under the common law principles of any state whose law is deemed to apply in this case.

**THIRTY-SECOND DEFENSE**

Johnson & Johnson specifically pleads as to any claim alleging a violation of consumer protection laws, all affirmative defenses available to Johnson & Johnson under the rules and statutes of any state whose law is deemed to apply in this case, and under the common law principles of any state whose law is deemed to apply in this case.

**THIRTY-THIRD DEFENSE**

The injuries and damages allegedly suffered in this action, which are denied, were not foreseeable to Johnson & Johnson given the state of scientific knowledge and state-of-the-art at the time of the alleged injuries. At all times relevant, the products at issue conformed to state-

of-the-art specifications and state-of-scientific knowledge for such products at that time, as well as all applicable statutes and regulations, including those of FDA.

**THIRTY-FOURTH DEFENSE**

Plaintiffs knowingly and voluntarily assumed any and all risks associated with the use of the products at issue in this case and thus the “last clear chance” and assumption of the risk doctrines bar in whole or in part the damages that plaintiffs seek to recover herein.

**THIRTY-FIFTH DEFENSE**

Plaintiffs’ claims are barred, in whole or in part, because Johnson & Johnson acted in good faith at all relevant times and the products at issue gave adequate warnings of all known or reasonably knowable risks associated with the use of the products.

**THIRTY-SIXTH DEFENSE**

At all relevant times herein, the products in question were manufactured and distributed with proper warnings, information, cautions, and instructions in conformity with generally recognized and prevailing standards in existence at the time.

**THIRTY-SEVENTH DEFENSE**

Plaintiffs’ inadequate warning claims are barred because the alleged risk of which plaintiffs claim is open, obvious, and/or a matter of common knowledge.

**THIRTY-EIGHTH DEFENSE**

Plaintiffs’ claims are barred in whole or in part because the products at issue were consistent with and/or exceeded consumer expectations.



**THIRTY-NINTH DEFENSE**

Plaintiffs' claims are barred in whole or in part because the products at issue were at all times properly prepared, packaged, and distributed, and were not defective or unreasonably dangerous.

**FORTIETH DEFENSE**

Adequate and complete warnings and instructions were provided with the products at issue. The products at issue were neither defective nor unreasonably dangerous when used according to their Instructions for Use.

**FORTY-FIRST DEFENSE**

At all relevant times, the warnings and instructions accompanying the products at issue were governed by and conformed with applicable federal statutes, rules and regulations; therefore, warnings and instructions relating to the products were presumptively adequate.

**FORTY-SECOND DEFENSE**

Plaintiffs' causes of action are barred by the learned intermediary doctrine.

**FORTY-THIRD DEFENSE**

Johnson & Johnson is not liable to plaintiffs because the end users of the products at issue, plaintiffs' physician(s), were sophisticated users of the products.

**FORTY-FOURTH DEFENSE**

Johnson & Johnson states that the sole proximate cause of the injuries and/or damages alleged by plaintiffs was the actions, omissions, or negligence of a person or persons, other than Johnson & Johnson, for whose actions, omissions, or negligence Johnson & Johnson is in no way liable. Plaintiffs are not, therefore, entitled to recover from Johnson & Johnson in this action. As to plaintiffs or to any other entity or person whose conduct or intervening

negligence resulted in the alleged injuries and/or damages of plaintiffs, if any, Johnson & Johnson expressly pleads the doctrines of assumption of risk, contributory negligence, comparative fault and/or comparative negligence, as well as the provisions of any applicable comparative fault and/or comparative negligence and/or contributory negligence statute, law or policy of the applicable states.

**FORTY-FIFTH DEFENSE**

The injuries and damages allegedly suffered in this action, which are denied, may have been caused, in whole or in part, by plaintiffs' own fault, which bars or proportionately reduces Johnson & Johnson's liability, if any, for plaintiffs' alleged damages.

**FORTY-SIXTH DEFENSE**

The plaintiffs voluntarily and unreasonably chose to encounter known dangers.

**FORTY-SEVENTH DEFENSE**

The liability of Johnson & Johnson, if any, for plaintiffs' non-economic loss must be apportioned or capped in accordance with the provisions of the law of the applicable state.

**FORTY-EIGHTH DEFENSE**

In the event Johnson & Johnson is held liable to plaintiffs, which liability is expressly denied, and any other co-defendants are also held liable, Johnson & Johnson is entitled to a percentage contribution of the total liability from said co-defendants in accordance with principles of equitable indemnity and comparative contribution and pursuant to any applicable contribution or apportionment statute, law or policy of the applicable states.

**FORTY-NINTH DEFENSE**

There is no causal relationship between Johnson & Johnson's conduct and the injuries and damages alleged by plaintiffs in the Complaint.

**FIFTIETH DEFENSE**

At all times mentioned herein, plaintiffs were negligent, careless and at fault and conducted themselves so as to contribute substantially to their alleged injuries, losses, and damages. Said negligence, carelessness and fault of plaintiffs bar in whole or in part the damages which plaintiffs seek to recover herein.

**FIFTY-FIRST DEFENSE**

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the products at issue in this case, if any, were solely caused by and attributable to the abnormal, unforeseeable, unintended, unreasonable, and improper use or misuse which was made of said products.

**FIFTY-SECOND DEFENSE**

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the products at issue in this case, if any, were not legally caused by the products at issue, but instead were legally caused by intervening and superseding causes or circumstances.

**FIFTY-THIRD DEFENSE**

Plaintiffs' alleged injuries, losses, or damages attributable to the products at issue in this case, if any, were caused by the acts or omissions of third parties for which Johnson & Johnson has no legal responsibility.

**FIFTY-FOURTH DEFENSE**

Johnson & Johnson expressly denies any third party engaging in the acts alleged by plaintiffs was acting as Johnson & Johnson's agent or servant, at the instruction of Johnson & Johnson, or within its control. Therefore, plaintiffs' claims, to the extent they seek to recover for the acts or omissions of such third parties, are barred in whole or in part as a matter of law.

**FIFTY-FIFTH DEFENSE**

Plaintiffs' causes of action are barred because the injuries and damages allegedly suffered in this action, which are denied, were due to an allergic, idiosyncratic or idiopathic reaction to the products at issue in this case, or by an unforeseeable illness, unavoidable accident, or preexisting condition, and/or another unrelated medical, genetic or environmental condition, disease or illness, without any negligence or culpable conduct by Johnson & Johnson.

**FIFTY-SIXTH DEFENSE**

Plaintiffs' claims are or may be barred by their failure to comply with conditions precedent to their right to recover.

**FIFTY-SEVENTH DEFENSE**

Plaintiffs' claims are barred, in whole or in part, by the doctrine of avoidable consequences.

**FIFTY-EIGHTH DEFENSE**

The claims of plaintiffs may be barred, in whole or in part, from recovery, due to spoliation of evidence and the failure to preserve evidence necessary to the determination of the claim.

**FIFTY-NINTH DEFENSE**

Plaintiffs' claims against Johnson & Johnson are barred by the doctrines of equitable estoppel, laches, consent, waiver, informed consent, release, unclean hands, res judicata, and collateral estoppel. Additionally, if any plaintiff had or has filed bankruptcy during the relevant time period of the events alleged in the Complaint or files for bankruptcy at some point in the future, the claims of any such plaintiff may be "property of the bankruptcy estate" which should be prosecuted by the bankruptcy trustee rather than plaintiff, or, if not disclosed by

plaintiff on the schedules and/or statement of financial affairs, may be barred by the doctrine of judicial estoppel.

**SIXTIETH DEFENSE**

Some or all of plaintiffs' claims may be barred by the statutes of limitations, prescription, and/or statutes of repose of the applicable states.

**SIXTY-FIRST DEFENSE**

To the extent plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred by *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

**SIXTY-SECOND DEFENSE**

Plaintiffs' alleged damages, if any, are barred in whole or in part by plaintiffs' failure to mitigate such damages.

**SIXTY-THIRD DEFENSE**

The sale, labeling and marketing of the products at issue in this litigation is not, and was not, likely to mislead or deceive the public.

**SIXTY-FOURTH DEFENSE**

Any strict liability cause of action for relief is subject to the limitations set forth in Restatement (Second) of Torts, Section 402A, comment k.

**SIXTY-FIFTH DEFENSE**

Plaintiffs' claims are barred in whole or in part under Section 402A, comment j and k of the Restatement (Second) of Torts.

**SIXTY-SIXTH DEFENSE**

Plaintiffs' claims are barred, in whole or in part, to the extent plaintiffs have released, settled, entered into an accord and satisfaction or otherwise compromised their claims by any means.

**SIXTY-SEVENTH DEFENSE**

Any recovery by plaintiffs must be reduced or offset by all amounts paid, payable by, or available from collateral sources.

**SIXTY-EIGHTH DEFENSE**

Plaintiffs' Complaint fails to state a claim upon which relief can be granted as to costs, attorneys' fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, rescission, unjust enrichment, disgorgement, fines, penalties or restitution.

**SIXTY-NINTH DEFENSE**

The Complaint fails to state facts sufficient to entitle plaintiffs to an award of punitive damages.

**SEVENTIETH DEFENSE**

No act or omission of Johnson & Johnson was malicious, oppressive, willful, wanton, reckless, or grossly negligent, and therefore any award of punitive damages is barred.

**SEVENTY-FIRST DEFENSE**

Plaintiffs' claims for pain and suffering are barred because they violate Johnson & Johnson's rights to procedural and substantive due process and equal protection as guaranteed by the Constitutions of the United States and the applicable states.

### **SEVENTY-SECOND DEFENSE**

The imposition of punitive or exemplary damages would violate Johnson & Johnson's constitutional rights, including but not limited to those under the due process clauses in the Fifth and Fourteenth Amendments to the Constitution of the United States, and the equivalent or correlative applicable provisions in the Constitutions, common law, public policy, applicable statutes and court rules of the applicable states to these amendments and the excessive fines clause in the Eighth Amendment to the Constitution of the United States and the double jeopardy clause in the Fifth Amendment to the Constitution of the United States. To the extent that punitive damages awarded to any plaintiff are (1) imposed by a jury that is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of such a punitive damages award; is not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment; is not expressly prohibited from awarding punitive damages, or determining the amount of an award thereof, in whole or in part, on the basis of invidious discriminatory characteristics, including the corporate status, wealth, or state of residence of defendant; or is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not define with sufficient clarity the conduct or mental state which makes punitive damages permissible; (2) are not subject to independent de novo review by the trial and appellate courts for reasonableness and the furtherance of legitimate purposes on the basis of objective legal standards and in conformity with the United States Constitution as amended or any applicable State constitution as amended; (3) imposed where state law is impermissibly vague, imprecise, or inconsistent; (4) subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount; or (5) imposed on the basis of anything other than Johnson &

Johnson's conduct within the State where each plaintiff resides, or in any other way subjecting Johnson & Johnson to impermissible multiple punishment for the same alleged wrong.

**SEVENTY-THIRD DEFENSE**

Johnson & Johnson specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts of the applicable states under the Due Process clause of the Fourteenth Amendment to the United States Constitution.

**SEVENTY-FOURTH DEFENSE**

With respect to plaintiffs' demand for punitive damages, Johnson & Johnson specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards that arise under *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and their progeny, as applied by the federal courts of appeals, together with all such standards applicable under any other state's law.

**SEVENTY-FIFTH DEFENSE**

Johnson & Johnson asserts the provisions of all applicable statutory caps on damages of any sort, including punitive, non-economic or exemplary damages, under the laws of the applicable states.

**SEVENTY-SIXTH DEFENSE**

Johnson & Johnson specifically pleads as to plaintiffs' claims for punitive damages, all affirmative defenses available to Johnson & Johnson under the rules and statutes of



any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

**SEVENTY-SEVENTH DEFENSE**

Johnson & Johnson specifically pleads as to plaintiffs' strict liability claims, all affirmative defenses available to Johnson & Johnson under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

**SEVENTY-EIGHTH DEFENSE**

Johnson & Johnson specifically pleads as to as to plaintiffs' negligence claims all affirmative defenses available to Johnson & Johnson under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

**SEVENTY-NINTH DEFENSE**

Johnson & Johnson hereby gives notice that it intends to rely upon and incorporate by reference any affirmative defenses that may be asserted by any co-defendant in this lawsuit.

**EIGHTIETH DEFENSE**

Johnson & Johnson reserves the right to assert any additional defenses and matters in avoidance, which may be disclosed during the course of additional investigation and discovery.

WHEREFORE, Johnson & Johnson denies that it is liable to the plaintiffs for damages or any other relief requested in the "Prayer for Relief" section of plaintiffs' Complaint,

including the Paragraph beginning “WHEREFORE” and subparagraphs (1)-(9) thereto. Johnson & Johnson prays that:

- (1) Plaintiffs take nothing by reason of their Complaint;
- (2) the Complaint be dismissed in its entirety and that a Judgment against plaintiffs and in favor of Johnson & Johnson be entered;
- (3) Johnson & Johnson be awarded its costs and expenses; and
- (4) this Court award Johnson & Johnson any other and general or specific relief as this Court may deem just and proper.

THIS, the 30<sup>th</sup> day of August, 2012.

Respectfully submitted,



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